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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 09/404,520
Filing Date: September 23, 1999
Appellant(s): CAO ET AL.

Thomas E. Holsten
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 16 January 2007 appealing from the Office action mailed 14 July 2006.

(1) Real Party of Interest

A statement identifying the real party of interest is contained in the brief.

(2) Related Appeals and Interferences

The following are the related appeals, interferences, and judicial proceedings known to the examiner which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal:

Appeal No. 2005-2746 (Application No. 09/404,520) mailed March 16, 2006 is the prior appeal of this case; a copy of the decision is provided in the Related Proceedings Appendix.

Appeal No. 2005-0795 (Application No. 09/747,357) mailed May 20, 2005 is an appeal on related subject matter; a copy of the decision is provided in the Related Proceedings Appendix.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

Claims 58-79 are pending. Claims 1-57 have been cancelled. Claims 58-79 stand finally rejected under 35 U.S.C. §103, but NOT under *res judicata*.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows: Claims 58-79 were not rejected under *res judicata* in view of the Board's decision mailed 16 March 2006 in the final Office action sent on 14 July 2006.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

Rodriguez-Tome et al. "The European Bioinformatics Institute (EBI) databases." Nucleic Acids Research. Volume 24, no. 1, 1996, pages 6-12.

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 58-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rodriguez-Tome et al. [Nucleic Acids Research, volume 24, no. 1, 1996, pages 6-12].

Claims 58-59 are drawn to methods of identifying a nucleotide sequence comprising providing and comparing a target sequence to a sequence stored in computer readable media having recorded thereon at least 100 nucleotide sequences including sequences selected from a larger group of sequences and their complements, and identifying the target sequence as being present on the computer readable media wherein the target sequence is selected from the same group of sequences mentioned above.

Rodriguez-Tome et al. teach the CD-ROM containing the EMBL nucleotide sequence database on column 1, page 6, lines 29-35, and column 2, page 6, lines 8-13, which states:

> The main activity of the group is the development, maintenance and distribution of a comprehensive database of nucleotide sequences. The EMBL nucleotide sequence database, produced in collaboration with GenBank... and the DNA database of Japan..., is Europe's primary nucleotide sequence data resource. Each of these three groups collect a portion of the total sequence data reported world-wide...
>
> The complete database is distributed in quarterly releases on compact disk (CD-ROM). The database including daily additions of all new and updated entries is available via the EBI network services... and from nodes of the European Molecular Biology Network...

Rodriguez-Tome et al. teach that the CD-ROM contains software for data retrieval on page 9, column 2, line 29 to page 10, column 1, line10 which states:

> Software for data query and retrieval is also provided on the CD-ROM. The programs EMBL-Search for Macintosh and SRS for DOS allow data access by entry name, accession number, keyword, citation, author name, taxonomic classification, database cross-reference, free text, and date. EMBL-Search also provides access to the Prosite and Enzyme databases, and enables navigation between related entries via cross-references built into these databases. It uses binary indices whose structure is documented and therefore available for other software systems. The SRS software is a DOS version (this is a port done by the EBI) of the sequence retrieval software used on the EBI network services. The sequence databases are also provided in NBRF format for use with software such as FASTA on Macintosh or MD-DOS systems.

Rodriguez-Tome et al. describe comparing the sequences of the user (i.e. target sequences) to the sequences in the EMBL nucleotide sequence database on page 10, column 2, lines 14-21 which state:

> The EBI provides a number of services that allow users to compare their own sequences against the most currently available data in the EMBL nucleotide sequence database and SWISS-PROT. BLITZ is based on the MPsrch program of Collins and Sturrock (Edinburgh University) which uses the Smith and Waterman algorithm for sensitive searches of the protein and nucleotide sequence databases. It is implemented on MasPar, a massively-parallel computer...

However, Rodriguez-Tome et al. do not teach the specific descriptive material in the database (i.e. Seq ID No.: 16207 through Seq ID No.: 27905) in instant claims 58 and 59.

The computer system and its method of use of identifying and analyzing sequences of biomolecules as stated in the instant set of claims differs from the claimed invention only in the content of the sequences used in the search and database. The MPEP states in section 2106.01:

> When nonfunctional descriptive material is recorded on some computer-readable medium, in a computer or on an electromagnetic carrier signal, it is not statutory and should be rejected under 35 U.S.C. 101. In addition, USPTO personnel should inquire whether there should be a rejection under 35 U.S.C. 102 or 103. USPTO personnel should determine whether the claimed nonfunctional descriptive material be given patentable weight. USPTO personnel must consider all claim limitations when determining patentability of an invention over the prior art. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). USPTO personnel may not disregard claim limitations comprised of printed matter. See Gulack, 703 F.2d at 1384, 217 USPQ at 403; see also Diehr, 450 U.S. at 191, 209 USPQ at 10. However, USPTO personnel need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

The above paragraph cites four court decisions which, when taken together, give the same message and theme regarding prior art and patentability of computerized media.

In *In re Gulack*, the CAFC ruled to give the appellant's claims patentability over the prior art because the mathematical educating device served as functional descriptive material, distinguishing it over the prior art.

As stated on page 1 of the decision:

> Printed matter that is not functionally related to substrate does not distinguish invention from prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight.

In *In re Ngai*, the CAFC did not give patentable weight over the prior art to an identical process of amplifying ribonucleic acids with a distinct set of printed instructions to execute this process because this set of instructions is not functional and therefore does not serve to distinguish it over the prior art.

In *In re Lowry*, the CAFC gives functional data structures patentability, and distinguishes these data structures and computer memory from nonfunctional printed matter.

As stated on page 1 of the decision:

> Claims for data processing system are neither anticipated by, nor obvious in view of, prior patents for database management system, since claimed invention, which employs plurality of attribute data objects having both hierarchical and non-hierarchical relationships, involves organization of information and its interrelationships which reference neither discloses nor suggests.

In *Diehr*, the US Supreme Court ruled analogously to the previous three cases with regards to mathematical equations. As stated at the bottom of page 10 of the ruling:

> when a claim containing a mathematical formula implements or applies that formula in a structure or process which, when considered as a whole, is performing a function which the patent laws were designed to protect (e.g., transforming or reducing an article to a different state or thing), then the claim satisfies the requirements of 35 U.S.C. 101. [i.e. is functional material]

The difference between Rodriguez-Tome et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer readable media functions, i.e., the sequence data does not reconfigure the computer readable media to perform a different function than the computer readable media of Rodriguez-Tome et al. Therefore, no patentable weight is given to the content of the database of sequences on the claimed computer readable media and its method of use. Rodriguez-Tome et al. shows all functional limitations of the claimed invention.

Claims 60-63 depend from claim 59 with the additional limitation of ranges describing the comparison of the target sequence and the sequences stored on the computer readable medium.

Claim 64 is dependent from claim 59 with the extra limitation of the target nucleotide sequence as being homologous to an ORF on the computer readable media.

Claim 65 is dependent form claim 59 with the additional limitation of limiting the size of the nucleotide sequence.

Claim 66 is dependent from claim 59 with the extra limitation of the target nucleotide sequence as being homologous to a sequence encoding all or a fragment of an *Emericella nidulans* protein on the computer readable media.

Since these additional claims are drawn to constraints of an embodiment of the independent claim (claim 59) given no patentable weight and since Rodriguez-Tome et

al. shows all functional limitations of instant claim 59, Rodriguez-Tome et al. shows all limitations given patentable weight in this set of instantly rejected claims.

Claim 66 is drawn to a method of detecting a nucleotide sequence comprising providing and comparing a target sequence to a sequence stored in computer readable media having recorded thereon at least 100 nucleotide sequences including sequences selected from a larger group of sequences and their complements, and identifying the target sequence as being present on the computer readable media wherein the target sequence is selected from the same group of sequences mentioned above.

The difference between Rodriguez-Tome et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer readable media functions, i.e., the sequence data do not reconfigure the computer readable media to perform a different function than the computer readable media of Rodriguez-Tome et al. Therefore, no patentable weight is given to the content of the database of sequences on the claimed computer readable media and its method of use. Rodriguez-Tome et al. shows all functional limitations of the claimed invention.

Claim 68 is dependent from claim 67 with the extra limitation of the target nucleotide sequence as being homologous to an ORF on the computer readable media.

Claim 69 is dependent form claim 67 with the additional limitation of limiting the size of the nucleotide sequence.

Claim 70 is dependent from claim 67 with the extra limitation of identifying a target sequence according to a degree of homology between the target sequence and the sequence stored on computer readable media.

Since these additional claims are drawn to constraints of an embodiment of the independent claim (claim 67) given no patentable weight and since Rodriguez-Tome et al. describes instant claim 67, Rodriguez-Tome et al. shows all limitations given patentable weight in this set of instantly rejected claims.

Claim 71 is drawn to a method of ranking a target nucleotide sequence by homology to a nucleotide sequence of *E. nidulans* comprising: providing and comparing a target sequence to a sequence stored in computer readable media having recorded thereon at least 100 nucleotide sequences including sequences selected from a larger group of sequences and their complements, and ranking the target sequence based on the percent homology to the nucleotide sequence of *E. nidulans*.

The difference between Rodriguez-Tome et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer readable media functions, i.e., the sequence data does not reconfigure the computer readable media to perform a different function than the computer readable media of Rodriguez-Tome et al. Therefore, no patentable weight is given to the content of the database on the claimed computer readable media and its method of use. Additionally, while the *E. nidulans* that represents types of sequences on which the target sequences are ranked alters the

nonfunctional descriptive material such that the sequence information for this organism is included, the altered information is nonfunctional descriptive material, and does not affect the prior art rejection. Rodriguez-Tome et al. shows all functional limitations of the claimed invention.

Claim 72 is dependent form claim 71 with the additional limitation of limiting the size of the nucleotide sequence.

Since these additional claims are drawn to constraints of an embodiment of the independent claim (claim 71) given no patentable weight and since Rodriguez-Tome et al. describes instant claim 71, Rodriguez-Tome et al. shows all limitations given patentable weight in this rejected claim.

Claim 73 is drawn to a method of detecting a nucleotide sequence comprising providing and comparing a target sequence to a sequence stored in computer readable media having recorded thereon at least 100 nucleotide sequences including sequences selected from a larger group of sequences and their complements, and identifying sequences having significant sequence identity to said nucleotide sequences on the computer readable medium, wherein the sequences stored in said computer readable medium function to facilitate the identification of the target sequence having significant sequence identity.

The difference between Rodriguez-Tome et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid

sequence database does not alter how the computer readable media functions, i.e., the database of the claimed computer readable media does not reconfigure the computer readable media to perform a different function than the computer readable media of Rodriguez-Tome et al. Therefore, no patentable weight is given to the content of the sequence data on the claimed computer readable media and its method of use. Rodriguez-Tome et al. shows all functional limitations of the claimed invention.

Claim 74 is dependent from claim 73 with the extra limitation of the nucleotide sequence being within the *Emericella nidulans* genome.

Claims 75-78 depend from claim 73 with the additional limitation of ranges describing the comparison of the target sequence and the sequences stored on the computer readable medium.

Since these additional claims are drawn to constraints of an embodiment of the independent claim (claim 73) given no patentable weight and since Rodriguez-Tome et al. describes instant claim 73, Rodriguez-Tome et al. shows all limitations given patentable weight in this rejected set of claims.

Claim 79 is drawn to a method of ranking a target nucleotide sequence by homology to a nucleotide sequence of *E. nidulans* comprising: providing and comparing a target fungal sequence to a sequence stored in computer readable media having recorded thereon at least 100 nucleotide sequences including sequences selected from a larger group of sequences and their complements, and identifying the function of said

target fungal nucleotide sequence based on homology to a nucleotide sequence in the *E. nidulans* genome based on said comparison.

The difference between Rodriguez-Tome et al. and the claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer readable media functions, i.e., the sequence data does not reconfigure the computer readable media to perform a different function than the computer readable media of Rodriguez-Tome et al. Therefore, no patentable weight is given to the content of the sequence data on the claimed computer readable media and its method of use. Additionally, while the *E. nidulans* that represents types of sequences on which the target fungal sequences are identified alters the nonfunctional descriptive material such that the sequence information for this organism is included, the altered information is nonfunctional descriptive material, and does not affect the prior art rejection. Rodriguez-Tome et al. shows all functional limitations of the claimed invention.

(10) Response to Argument

Remarks:

There are three sections of the arguments by the appellant. The first section on page 5 summarizes the arguments of the latter two sections. The second section on pages 6-7 argues that the amended claims are not subject to the previous decision by the Board. The third section on pages 7-12 argues that the claimed methods are not obvious over the instantly applied prior art.

Arguments addressed:

The appellant begins the arguments on page 5 by stating:

> As the amended claims differ from the previously appealed claimed, the rejection of the claims under *res judicata* is improper.

However, this statement is not accurate. The final Office action of 14 July 2006 never rejected the set of claims under *res judicata*. Instead, the Office action stated on pages 2-3:

> A board of Patent Appeals and Interferences decision in an application has *res judicata* effect and is the "law of the case" and is thus controlling in that application and any subsequent, related application....
>
> In this case, the amendments made to the set of claims filed on May 16, 2006 are still governed by the decision of the Board of Patent Appeals and Interferences decision of March 16, 2006. The response to the arguments and amendments to the claims made on May 16, 2006, can be addressed using this Board of Patent Appeals and Interferences decision of March 16, 2006.

Consequently, while the claims are amended after the decision of the Board of Patent Appeals and Interferences of 16 March 2006, the amendments of the appellant do not change the ground of rejection from the previous Office action (in this case, the Examiners' Answer of 19 November 2004). Therefore, a rejection under *res judicata* does not occur because the set of claims are amended and not identical. The final Office action of 14 July 2006 never states that a rejection under *res judicata* exists. The Office action merely states that there is a "*res judicata* effect" in that the ground and reasons for rejection are identical to that of the decision of the Board of Patent Appeals and Interferences of 16 March 2006 even though the set of claims is amended.

Appellant continues on pages 6-7 of the appeal brief by indicating the amendments to the set of claims in order to show that a rejection under *res judicata* is not proper. These arguments are found to be persuasive, but moot, because a rejection under *res judicata* never existed in the prosecution history of this case.

Appellant continues on page 7 of the appeal brief by stating:

> ...the Board did not base its decision of the target sequence being compared to at least one of the sequences of SEQ ID NO: 16207 to 27905. Instead, as suggested by the Board's claim interpretation of claim 58, the target sequence was compared to a database of at least 100 nucleotide sequences, at least one of which is included in this group.

The argument of claim interpretation in relation to how the amendments to the set of claims affect the functionality of the data will be addressed in the section of the "Reply to Arguments" governing the obviousness prior art rejection.

With regard to the obviousness rejection, the first argument of the applicant on pages 8-10 of the appeal brief is that the recited sequences are functional descriptive material.

On pages 8-9 of the appeal brief, appellant discusses *In re Gulack* and *In re Lowry*, by quoting the following three passages (the first two are from *In re Gulack* and the third is from *In re Lowry*):

> All claimed limitations must be considered when determining patentability.
>
> Differences between an invention and the prior art against it cannot be ignored merely because those differences reside in the content of the printed matter.
>
> ...printed matter cases have no factual relevance where the invention as defined by the claims required that the information be processed not by mind by a machine, the computer.

However, as quoted from the rejections above, *In re Gulack* (top) and *In re Lowry* (bottom) also state the following:

> Printed matter that is not functionally related to substrate does not distinguish invention from prior art in terms of patentability; although printed matter must be considered, in that situation it may not be entitled to patentable weight.
>
> Claims for data processing system are neither anticipated by, nor obvious in view of, prior patents for database management system, since claimed invention, which employs plurality of attribute data objects having both hierarchical and non-hierarchical relationships, involves organization of information and its interrelationships which reference neither discloses nor suggests.

Consequently, while *In re Gulack* states that all claimed limitations must be considered when determining patentability, the same decision indicates after being considered these limitations may not be given patentable weight due to the lack of functionality of the limitations.

Furthermore, *In re Lowry* is clear that if a set of data assists the function of the system on which it operated, it is given patentable weight.

In the instant case, the sequence information is not given patentable weight because it is not functional and does not affect the operation of the computer readable media on which it exists.

On page 9 of the appeal brief, the appellant argues first that the sequences exhibit a functional relationship with the computer readable medium because of the goal of the claim to "facilitate the identification, detection or ranking of nucleotide sequences from *E. nidulans* within the sequences stored on computer readable medium." Consequently, appellants indicate that this existence of a biological function of the algorithm causes the sequences on the computer readable medium to be functional. However, while it is agreed that the execution of this method results in a more biological understanding of the function of the sequences, it is not agreed and nowhere stated by the applicant how the sequence data affects the functional operation of the computer

readable media. This functionality in terms of hardware and not functionality in terms of biology is what is required by *In re Lowry* to determine if the sequence data is functional and should be given patentable weight.

Appellant states on page 10 of the appeal brief:

> The claimed methods would not achieve their purposes (identification, detection or ranking) without the comparison to at least one of the recited SEQ ID NOs recorded on a computer readable medium. As previously argued, the claimed methods allow for the easy identification, ranking or detection of nucleotide sequences selected from the group consisting of SEQ ID NO: 16207 to SEQ ID NO: 27905 and complements thereof.

However, automation and ease of operation do not make a method or system functional. It is possible to accomplish the identical method manually resulting in the same determination of biological function, but in a longer period of time. Additionally, automation of a process does not result in patentability. As stated in MPEP section 2144.04:

> *In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958) (Appellant argued that claims to a permanent mold casting apparatus for molding trunk pistons were allowable over the prior art because the claimed invention combined "old permanent-mold structures together with a timer and solenoid which automatically actuates the known pressure valve system to release the inner core after a predetermined time has elapsed." The court held that broadly providing an automatic or mechanical means to replace a manual activity which accomplished the same result is not sufficient to distinguish over the prior art.).

With regard to the obviousness rejection, the second argument of the applicant on pages 10-12 of the appeal brief is that the Rodriguez-Tome et al. reference does not teach or suggest all of the elements of the instantly rejected claims.

Appellant summarizes the missing elements of the instantly rejected claims by stating on page 12 of the appeal brief:

> In the present case, the deficiencies in the teachings of Rodriguez-Tome et al. regarding the nucleotide sequence in a computer readable medium having recorded thereon at least 100

> nucleotide sequences including sequences selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof are not compensated by any other references.

However, in making this assertion, the appellant is assuming that this data is functional and given patentable weight.

Appellant continues to argue functionality on pages 10-11 of the appeal brief by stating:

> As the specification discloses, the sequences are isolated from the filamentous fungus *Emericella nidulans*, which is frequently used as a model eukaryotic organism to investigate a variety of biological mechanisms. See specification at page 2, lines 5-10.

Again, appellant is arguing the biological functionality of the sequences is what causes the computer readable media on which they are located to be functional. In this instance, appellant is using limitations of the specification and not the instantly rejected set of claims.

Appellant has no arguments specific to the dependent claims of the instant case in the appeal brief.

In summary, despite the scientific significance of the sequence data, the lack of ability of the sequence to affect the function of or improve the performance of the computer readable media on which it resides causes the data to be viewed legally as nonfunctional data. Since the data is nonfunctional, it is not given patentable weight in the instant set of claims; this allows for the application of the study of Rodriguez-Tome et al. to describe the instant set of claims.

(11) Related Proceeding(s) Appendix

Copies of the court or Board decision(s) identified in the Related Appeals and Interferences section of this examiner's answer are provided herein.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Russell S. Negin, Ph.D.
Examiner
Art Unit 1631
ms May 21, 2007

5/21/07

Conferees:

29 May 2007

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte BRIAN ZAMBROWICZ and ARTHUR T. SANDS

Appeal No. 2005-0795
Application No. 09/747,357

ON BRIEF

Before WILLIAM F. SMITH, MILLS, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 13 and 14, the only claims remaining. Claims 13 and 14 read as follows:

13. A computer-based system for identifying nucleic acid fragments of the human genome of commercial importance comprising the following elements:

a) a data storage means comprising a sense or antisense sequence of at least about 150 contiguous nucleotides from SEQ ID NO:9;

b) search means for comparing a target sequence to each of the sequences of the data storage means of step a) to identify homologous sequence(s); and

c) retrieval means for obtaining said homologous sequence(s) of step (b).

14. A method for identifying nucleic acid fragments of the human genome of commercial importance, comprising comparing a target sequence comprising a putative nucleic acid fragment of the human genome of commercial importance to a data storage means comprising SEQ ID NO:9 utilizing the computer system of claim 13, wherein the presence of a homologous sequence verifies the nucleic acid fragment of the human genome of commercial importance.

The examiner relies on the following reference:

Bailey Jr., et al. (Bailey), "Analysis of EST-Driven Gene Annotation in Human Genomic Sequence," Genome Research, Vol. 8, pp. 362-376 (1998)

Claims 13 and 14 stand rejected under 35 U.S.C. §§ 101 and 112, first paragraph, for lack of patentable utility.

Claims 13 and 14 stand rejected under 35 U.S.C. § 112, first paragraph, for lack of an adequate written description in the specification.

Claims 13 and 14 stand rejected under 35 U.S.C. § 103 as obvious in view of Bailey.

We affirm the rejections for obviousness and lack of utility and do not reach the rejection for inadequate written description.

Background

The specification discloses one thousand "nucleic acid sequences that partially define the scope of human exons." Page 1. These sequences, referred to generically as "gene trapped sequences" or GTSs, are shown in SEQ ID NOs 9 to 1008. See page 2, lines 16-18. The specification tells us that the GTSs were isolated using a technique ("gene trapping") that was designed to specifically isolate parts of exons. See pages 5-6 and 80-86. Since exons are the protein-encoding parts of genes, each of the disclosed

sequences would be expected to encode part of a protein that is expressed in human cells.

SEQ ID NO:9, the first of the one thousand disclosed GTS sequences, is 474 nucleotides long. The specification does not disclose the amino acid sequence encoded by SEQ ID NO:9 (or any of the other 999 sequences), but states that

> the disclosed GTSs contain open reading frames (present in one of the three reading frames in either orientation of the sequence). . . . [T]he actual reading frame and amino acid sequence of a given nucleotide sequence may be determined by in vitro synthesis of a portion of an oligopeptide comprising a possible amino acid sequence and preparing antibodies to the oligopeptide. If the antibodies react with cells from which the GTS of interest was derived, the reading frame is likely correct.

Page 9, lines 3-18. In addition, the specification discloses that the GTS sequences "typically contain only a portion of the mature RNA transcript . . ., and therefore such clones may only encode a portion of the polypeptide of interest." Page 10, lines 20-23.

The specification asserts that the GTS polynucleotides have numerous uses. In particular, the specification

> contemplates methods of analyzing biopolymers . . . sequence information comprising the steps of loading a first polymer sequence into or onto an electronic data storage medium (e.g., digital or analogue versions of electronic, magnetic, or optical memory, and the like) and comparing said first sequence to at least a portion of one of the polynucleotide sequences, or amino acid sequence encoded thereby, that is first disclosed in, or otherwise unique to, SEQ ID NOS:9-1,008.

Page 2, lines 24-32. See also pages 77-80 ("Computer related embodiments").

Discussion

Claim 13 is directed to a "computer-based system for identifying nucleic acid fragments of commercial importance" comprising a data storage means comprising at least 150 nucleotides of the sequence shown in SEQ ID NO:9, search means for

comparing a target sequence to the sequence(s) in the data storage means, and a retrieval means for obtaining sequences homologous to SEQ ID NO:9. Claim 14 is directed to a method for identifying sequences using the system of claim 13.

The examiner rejected the claims on the basis that they lacked patentable utility, that they lacked adequate descriptive support in the specification, and that they were not patentably distinct from the prior art.

1. Utility

The examiner rejected the claims for lack of utility, because

> [t]he specification states on page[ ]76 that the claimed computer system may be used to identify corresponding introns and exons in genomic sequences. The utility contemplated by the applicants involves further research on SEQ ID NO:9 without a result that has a practical utility. . . . Identifying introns and exons of genes of interest for further research does not define a "real world" context o[f] use.

Examiner's Answer, pages 3-4. The examiner concluded that "[t]he claimed computer system and its method of use have only been disclosed as useful for performing further research on SEQ ID NO:9 and genomic sequences that correspond to SEQ ID NO:9. Because this is equivalent to the object of scientific research and object of use testing discussed by the Supreme Court [in Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966)], the claimed invention does not have patentable utility." Id., page 6.

We agree with the examiner that the specification does not disclose a utility sufficient to satisfy 35 U.S.C. § 101. Brenner v. Manson, cited by the examiner, provides the starting point for any analysis of utility in the context of compounds with poorly characterized biological properties. At issue in Brenner was a claim to "a chemical process which yields an already known product whose utility—other than as a

possible object of scientific inquiry—ha[d] not yet been evidenced." Id. at 529, 148 USPQ at 693.

The Brenner Court noted that although § 101 requires that an invention be "useful," that "simple, everyday word can be pregnant with ambiguity when applied to the facts of life." Id. at 529, 148 USPQ at 693. Thus,

> [it] is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes. Even if we knew precisely what Congress meant in 1790 when it devised the "new and useful" phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man's grasp and where little or nothing is wholly beyond the pale of "utility"—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.[1]

The Court concluded that "[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field." Id. at 534-35, 148 USPQ at 695.

The Court considered and rejected the applicant's argument that attenuating the requirement of utility "would encourage inventors of new processes to publicize the event for the benefit of the entire scientific community, thus widening the search for uses and increasing the fund of scientific knowledge." The Court noted that, while there

[1] The invention in Brenner was a process, but the Court noted that its holding "would apply equally to the patenting of the product produced by the process." Id. at 535, 148 USPQ at 695-96.

is value to encouraging disclosure, "a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute." Id. at 534, 148 USPQ at 695.

The Court pointed out that it did not "mean to disparage the importance of contributions to the fund of scientific information short of the invention of something 'useful,'" and that it was not "blind to the prospect that what now seems without 'use' may tomorrow command the grateful attention of the public." Id. at 535-36, 148 USPQ at 696. Those considerations did not sway the Court, however, because "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion." Id.

Subsequent decisions of the CCPA and the Court of Appeals for the Federal Circuit have further defined the meaning of § 101's utility requirement. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). The invention claimed in Kirk was a set of steroid derivatives said to have valuable biological properties and to be of value "in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice." Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility. In response, the applicants submitted an affidavit which purportedly "show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests." Id. at 939, 153 USPQ at 51.

The court held that "nebulous expressions [like] 'biological activity' or 'biological properties'" did not adequately convey how to use the claimed compounds. Id. at 941,

153 USPQ at 52. Nor did the applicants' affidavit help their case: "the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know 'how to use' the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are." Id. at 942, 153 USPQ at 53.

The Kirk court held that an earlier CCPA decision, holding that a chemical compound meets the requirements of § 101 if it is useful to chemists doing research on steroids, had effectively been overruled by Brenner. "There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher' was recognized, and clearly rejected, by the Supreme Court" in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

More recently, in In re Ziegler, 992 F.2d 1197, 26 USPQ2d 1600 (Fed. Cir. 1993), the Federal Circuit considered the degree of specificity required to show utility for a claim to polypropylene. The U.S. application on appeal in Ziegler claimed priority to a German application filed in 1954. "In the German application, Ziegler disclosed only that solid granules of polypropylene could be pressed into a flexible film with a characteristic infrared spectrum and that the polypropylene was 'plastic-like.'" Id. at 1203, 26 USPQ2d at 1605. "Ziegler did not assert any practical use for the polypropylene or its film, and Ziegler did not disclose any characteristics of the polypropylene or its film that demonstrated its utility." Id. The court held that the German application did not satisfy the requirements of § 101 and therefore could not be relied on to overcome a rejection based on an intervening reference. See id., 26

USPQ2d at 1606. "[At] best, Ziegler was on the way to discovering a practical utility for polypropylene at the time of the filing of the German application; but in that application Ziegler had not yet gotten there." Id., 26 USPQ2d at 1605.

On the other hand, the CCPA reversed a rejection for lack of utility in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980). The applicant in Jolles claimed pharmaceutical compositions that were disclosed to be useful in treating acute myeloblastic leukemia. See id. at 1323, 206 USPQ at 886. The active ingredients in the compositions were closely related to daunorubicin and doxorubicin, both of which were "well recognized in the art as valuable for use in cancer chemotherapy." Id., 206 USPQ at 887. The applicant also submitted declaratory evidence showing that eight of the claimed compositions were effective in treating tumors in a mouse model, and one was effective in treating humans. See id. at 1323-24, 206 USPQ at 887-88. The court noted that the data derived from the mouse model were "relevant to the treatment of humans and [were] not to be disregarded," id. at 1327, 206 USPQ at 890, and held that the evidence was sufficient to support the asserted therapeutic utility. See id. at 1327-28, 206 USPQ at 891.

The Federal Circuit held in Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985), that in vivo testing (as in Jolles) was not necessarily required to show utility for a pharmaceutical. The Cross court stated that "[it] is axiomatic that an invention cannot be considered 'useful,' in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious." Id. at 1044, 224 USPQ at 742 (citing Brenner). The court

> perceive[d] no insurmountable difficulty, under appropriate circumstances, in finding that the first link in the screening chain, in vitro testing, may establish a practical utility for the compound in question." Id. at 1051, 224 USPQ at 748. Successful in vitro testing could provide an immediate benefit to the public, by "marshal[ling] resources and direct[ing] the expenditure of effort to further in vivo testing of the most potent compounds . . ., analogous to the benefit provided by the showing of an in vivo utility.

Id. On the facts of that case – successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds – the court held that in vitro activity was sufficient to meet the requirements of § 101. See id.

The Federal Circuit confirmed in In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995), that human testing is not necessary to establish utility for a method of treatment. The invention claimed in Brana was a group of compounds disclosed to have antitumor activity. See id. at 1562, 34 USPQ2d at 1437-38. The claimed compounds were disclosed to have higher antitumor activity than related compounds known to have antitumor activity, and the applicants provided declaratory evidence of in vivo activity against tumors in a mouse model. See id., 34 USPQ2d at 1438. The court held that these data were sufficient to satisfy § 101; usefulness in patent law does not require that the invention be ready to be administered to humans. See id. at 1567, 34 USPQ2d at 1442.

Several lessons can be drawn from the cases applying Brenner. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, the steroid compound at issue in Brenner was

useful as a possible object of scientific inquiry, and the polypropylene claimed in Ziegler was useful for pressing into a flexible film, yet both lacked sufficient utility to satisfy § 101. See Brenner, 383 U.S. at 529, 148 USPQ at 696; Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

Rather than setting a de minimis standard, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met by pharmaceutical compositions shown to be useful in mouse models and in humans for treating acute myeloblastic leukemia (Jolles); by evidence showing successful in vitro testing supplemented by similar in vitro and in vivo activities of structurally similar compounds (Cross); and by evidence showing in vivo antitumor activity in mice, combined with a disclosure that the claimed compounds had higher antitumor activity than a related compound known to have antitumor activity (Brana).

By contrast, Brenner's standard has been interpreted to mean that "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" would not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner). Likewise, a disclosure of a "plastic-like" polypropylene capable of being pressed into a flexible film was held to show that the applicant was "at best . . . on the way to discovering a practical utility for polypropylene at the time of the filing," but not yet there. Ziegler, 992 F.2d at 1203, 26 USPQ2d at 1605.

In this case, the examiner rejected the claims on the basis that the disclosed utility for the claimed computer system and method – identifying the positions of introns and exons in the genomic locus corresponding to SEQ ID NO:9 – is not a substantial

utility sufficient of satisfy § 101 as interpreted by the Brenner Court. See the Examiner's Answer, pages 3-6.

Appellants argue that the claimed computer system and method are useful because the polynucleotide having the sequence of SEQ ID NO:9 is useful. Appellants argue that the polynucleotide of SEQ ID NO:9 is useful, among other things, for assessing gene expression using "DNA chips" and for identifying the chromosomal location of the gene corresponding the SEQ ID NO:9. See the Appeal Brief, pages 9-11.

We do not agree with Appellants that the utilities asserted for the polynucleotide of SEQ ID NO:9, even if they were adequate to satisfy § 101, would support the patentability of the present claims. The claims are directed to a computer system comprising "a data storage means comprising a sense or antisense sequence of at least about 150 contiguous nucleotides from SEQ ID NO:9" (claim 13) and a method of using the computer system to identify similar sequences in a database (claim 14). The claims are not directed to the polynucleotide of SEQ ID NO:9 or a gene chip comprising the polynucleotide of SEQ ID NO:9. Thus, even if the polynucleotide of SEQ ID NO:9 would be useful because it could be attached to a chip and used to measure gene expression data,[2] that potential utility would not apply to the instant claims because the polynucleotide on which utility is premised is not a part of the instantly claimed computer system and method.[3]

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[2] We need not reach this issue in this case, but in other appeals involving commonly assigned cases, we have concluded that using a polynucleotide as a component of a gene chip does not satisfy the requirements of 35 U.S.C. § 101. See, e.g., the decision on appeal in application 09/460,594 (Appeal No. 2003-1528), mailed June 30, 2004.

[3] "SEQ ID NO:9" and "a polynucleotide having the sequence shown in SEQ ID NO:9" refer to different things. See the discussion on pages 16-17, infra.

Appellants also argue that the claimed computer system is useful for identifying intron/exon boundaries. Appeal Brief, page 7. See also page 8: "In disclosing a biologically validated exon splice junction, . . . the present computer system provides results superior to patented bioinformatics systems used in conjunction with genomic sequence data alone."

The specification states that

> [i]n order to analyze the described GTSs, or overlay the described GTSs on human genomic sequence, a computer based system can be used. A search program for accessing a human genome database is used. The sequence from any one of SEQ ID NOS:9-1,008 or a full-length clone is compared and aligned to the human genome allowing for gaps. Where homologous genomic sequence is found, a given GTS or full length sequence will typically identify several dispersed regions of homology, and the intervening gaps will generally constitute introns.
>
> The GTSs can also be used to identify the specific locations of exon splice junctions. These can be particularly important in the study of disease and cancer. Splice junctions can often be hot spots for erroneous events leading to these disease states.

Page 76, lines 12-23.

We agree with the examiner that the potential use of the claimed computer system and method in identifying intron/exon boundaries does not meet the utility requirement of 35 U.S.C. § 101. Mapping the intron/exon boundaries in the gene corresponding to SEQ ID NO:9 does not provide a specific benefit in currently available form because the specification provides no meaningful guidance regarding how to use such information in any practical way. Assume, for example, that the claimed computer system was used to show that the gene corresponding to SEQ ID NO:9 has an exon splice junction between nucleotides 103 and 104: the specification provides no guidance on how such information would allow those skilled in the art to use the claimed

polynucleotides in a specific, substantial way. By contrast, if the specification disclosed, for example, that an exon splice junction in the gene corresponding to SEQ ID NO:9 was a hot spot for recombinations associated with cancer, the claimed computer system and method might have utility in disease diagnosis. However, in the absence of a specific use for the resulting data, using the claimed computer system to determine exon splice-junctions is not a specific and substantial utility.

In effect, Appellants' position is that the claimed computer system and method are useful because those of skill in the art could use them to make sequence comparisons and figure out for themselves what any observed results might mean. We do not agree that such a disclosure provides a "specific benefit in currently available form." Rather, the instant case seems analogous to Brenner. In Brenner, the applicant claimed a method of making a compound but disclosed no utility for the compound. 383 U.S. at 529, 148 USPQ at 693. The Court held that a process lacks utility if it produces a product that lacks utility. Id. at 534, 148 USPQ at 695. Here, Appellants claim a product and method asserted to be useful for generating exon splice-junction data, but the specification does not disclose any use for those data. Just as the process claimed in Brenner lacked utility because the specification did not disclose how to use the end-product, the claims here lack utility, based on their use in mapping exon splice-junctions because the specification does not disclose how to use the SEQ ID NO:9-specific data generated by the claimed computer system or method.

Finally, Appellants argue that "the present claims are directed to a computer system, not merely nucleic acid sequences. Appellants note that the Office has issued numerous patents directed to computer systems comprising nucleotide sequences. . . .

Since U.S. Patents are presumed valid under all sections of 35 U.S.C., including § 101, the present invention concerning a computer system, although distinct from those listed above, must meet the utility requirement of 35 U.S.C. § 101." Appeal Brief, page 13.

This argument lacks merit. Appellants have made no effort to show that the facts of any of the patents cited in the Appeal Brief are comparable to those at issue here. Specifically, Appellants have not shown that any of the cited patents included a claim to a computer system including, or a method using, a single polynucleotide sequence to identify similar sequences, where the specification discloses no data characterizing the known sequence. Thus, Appellants have not shown that our decision in this case is inconsistent with decisions made in other cases.

In any event, every case is decided on its own facts. See, e.g., In re Giolito, 530 F.2d 397, 400, 188 USPQ 645, 648 (CCPA 1976): "We reject appellants' argument that the instant claims are allowable because similar claims have been allowed in a patent. It is immaterial whether similar claims have been allowed to others." That other patents have been issued, based on different facts, is not evidence that the examiner's decision in this case, on these facts, is in error. The rejection for lack of utility is affirmed.

2. Obviousness

The examiner rejected claims 13 and 14 as obvious in view of Bailey, because Bailey teaches a computer system and method of using such a system to compare DNA sequences. The examiner acknowledged that Bailey does not teach SEQ ID NO:9, but reasoned that this difference

> constitutes non-functional descriptive material because the content of the nucleic acid sequence database does not alter how the computer system functions, i.e., the database of the claimed computer system does not

> reconfigure the computer system to perform a different function than the computer system of Bailey et al. Therefore no patentable weight is given to the content of the database on the claimed computer system and its method of use.

Examiner's Answer, page 11.

We agree with the examiner that Bailey's disclosure makes claims 13 and 14 unpatentable. Bailey discloses a computer-based system and method of comparing DNA sequences that reasonably appear to meet all the limitations of claims 13 and 14 with the exception of SEQ ID NO:9. See page 374, under the headings "Computational Resources", "Blast Similarity Searches", and "WU-BLAST2 Comparisons". Because the claims differ from the prior art only in the specific nucleotide sequence stored on the computer and compared to the target sequence, they are not patentable over the prior art.

The facts of this case are similar to those of In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004). In that case, the claim at issue was directed to a kit that differed from the prior art only in the contents of the written instructions that accompanied the kit. Id. at 1338, 70 USPQ2d at 1863. The court concluded that the contents of the instructions did not distinguish the claimed kit from kits known in the art, notwithstanding the difference in the printed matter. Id., 70 USPQ2d at 1864.

The same analysis applies here. Claims 13 and 14 differ from the computer system and method disclosed by Bailey only in the specific sequence written into the data storage means of claim 13 and compared with a target sequence in claim 14. As in Ngai, there is no functional relationship between the contents of the printed matter and the substrate on which it is encoded. Cf. In re Gulack, 703 F.2d 1381, 217 USPQ

401 (Fed. Cir. 1983). Thus, the content of the printed matter (i.e., SEQ ID NO:9) is not entitled to patentable weight and does not distinguish the claims from the prior art.

It is true that the application in Ngai included method claims and product claims; the method claims were found to be allowable even though the product claims were not. 367 F.3d at 1338, 70 USPQ2d at 1863. The method claims in Ngai, however, did not involve the printed matter (instructions) that failed to distinguish the kit claims from the prior art. See id. Here, the product of claim 13 and the method of claim 14 differ from the prior art in the same way: the inclusion of SEQ ID NO:9 in a known computer system and method. Thus, both the product and method are unpatentable.

Appellants argue that "the difference between Bailey and the present invention, specifically SEQ ID NO:9, is not 'nonfunctional descriptive material'". Appeal Brief, page 19. Appellants reason that "the MPEP details that non-functional descriptive material is not patentable ('(t)he policy that precludes the patenting of nonfunctional descriptive material would be easily frustrated if the same descriptive material could be patented when claimed as an article of manufacture' (MPEP at 2100-14, emphasis added). As nucleic acids are patentable, this also supports the position that SEQ ID NO:9 is functional descriptive material." Id.

This argument is not persuasive. Nucleic acids are patentable, but SEQ ID NO:9 is not a nucleic acid – it is an abstract representation of the structure of a nucleic acid. That is, nucleic acids are not made up of A's, T's, G's, and C's, the way SEQ ID NO:9 is; nucleic acids are made up of the bases adenine, thymine, guanine, and cytosine, connected to sugar residues, which in turn are connected by phosphodiester bonds. The compound represented by SEQ ID NO:9 is patent-eligible subject matter, but SEQ

ID NO:9 itself is not. The potential patentability of the compound represented by SEQ ID NO:9 does not support Appellants' position that SEQ ID NO:9 is functional descriptive material.

Appellants also argue that the examiner erred in asserting that "the difference between Bailey and the presently claimed invention constitutes non-functional descriptive material because the content of the nucleic acid sequence database 'does not alter how the computer functions.'" Appeal Brief, page 19. Appellants point to issued patents that include a "comparison function" such as patents involving the use of passwords to allow a user access to a computer and computer virus scanning programs. Appellants reason that "[i]n these and similar patents, the computer compares an input to authorized passwords or known computer viruses, in the same way that the present computer system compares an input sequence to a biologically verified coding sequence (SEQ ID NO:9)." Id., page 20.

This argument is also unpersuasive. We have reviewed the patents cited in the Appeal Brief but do not agree that they support the patentability of the instant claims. The examiner's position is that the instant claims differ from the prior art only in the content (i.e., SEQ ID NO:9) that is being compared in the claimed computer system or method. Appellants have not alleged, and we have not found, that the patents cited in the Appeal Brief claim products or methods that differ from the prior art only in the content (password or computer virus) that is compared in the performance of the claimed security or virus-scanning program. Since the claims in the cited patents appear to differ from the prior art in more than the mere content of the data being compared, the cited patents do not support the patentability of the instant claims.

3. Written description

The examiner also rejected claims 13 and 14 on the basis that they were not adequately described in the specification. Since we have already concluded that claims 13 and 14 are unpatentable for lack of utility and for obviousness, we need not consider whether they are also unpatentable for lack of adequate written description. Therefore, we do not reach the rejection based on inadequate written description.

Summary

The computer system of claim 13 and the method of claim 14 lack patentable utility and are not patentably distinct from the prior art. We therefore affirm the examiner's rejections under 35 U.S.C. §§ 101 and 103.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

William F. Smith
Administrative Patent Judge

Demetra J. Mills
Administrative Patent Judge

Eric Grimes
Administrative Patent Judge

) BOARD OF PATENT
) APPEALS AND
) INTERFERENCES

EG/jlb

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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte YONGWEI CAO, AZITA GHODSSI, GREGORY J. HINKLE, JAMES D. McININCH, WILLIAM E. TIMBERLAKE, and JAEHYUK YU

Appeal No. 2005-2746
Application No. 09/404,520

HEARD December 15, 2005

Before SCHEINER, GRIMES, and ADAMS, Administrative Patent Judges.

Opinion by GRIMES, Administrative Patent Judge.
Dissenting opinion by ADAMS, Administrative Patent Judge.

DECISION ON APPEAL

This appeal involves claims to a method of determining whether a target nucleic acid is similar to other, specified nucleic acids. The examiner has rejected the claims as obvious in view of the prior art. We have jurisdiction under 35 U.S.C. § 134. We conclude that the obviousness of the claimed method does not depend on which sequences are being compared. We therefore affirm the rejection.

Background

The specification discloses "nucleic acid molecules representing the genome of the filamentous fungus, Emericella nidulans (previously and still sometimes called

Aspergillus nidulans) and, in particular, to nucleic acid sequences corresponding to genes, promoters, other regulatory elements, and introns found in the E. nidulans genome." Page 1. "The nucleic acid sequences disclosed . . . are believed to represent substantially all, or at least a major part, of the genes in the E. nidulans genome." Page 3. One "aspect of th[e] invention comprises a set of about 12,000 genes or partial genes of the E. nidulans genome including genes represented by SEQ ID NO: 16207 through SEQ ID NO: 27905." Page 4.

The specification also "provides computer readable media having recorded thereon one or more of the nucleotide sequences provided by this invention and methods for using such media, e.g., in searching to identify genes associated with nucleic acid sequences." Page 6. See also page 39:

> [T]he computer-based systems of the present invention comprise a data storage means having stored therein a nucleotide sequence of the present invention and the necessary hardware means and software means for supporting and implementing a search means. . . . Search means are used to identify fragments or regions of the sequence of the present invention that match a particular target sequence or target motif. A variety of known algorithms are disclosed publicly and a variety of commercially available software for conducting search means are available [and] can be used in the computer-based systems of the present invention. Examples of such software include, but are not limited to, MacPattern (EMBL), BLASTIN and BLASTIX (NCBIA).

Discussion

1. Claim construction

Claims 58-72 are pending and stand rejected. The claims will stand or fall together, because Appellants did not argue them separately in the Appeal Brief. See (then-applicable) 37 CFR § 1.192(c)(7). We will focus on claim 58, which is representative and reads as follows:

58. A method of identifying a nucleotide sequence comprising comparing a target sequence to a sequence stored in computer readable medium having recorded thereon at least 100 nucleotide sequences including sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, and identifying said target sequence as being present in the computer readable medium.

Thus, claim 58 is directed to a method that comprises comparing a target sequence to a database of at least 100 nucleotide sequences, at least one of which is included in the group of sequences represented by SEQ ID NOs 16207 to 27905. The method implicitly requires that computer hardware and software carry out the comparison, because the nucleotide sequences must be recorded on a computer-readable medium.

2. Obviousness

The examiner rejected claims 58-72 under 35 U.S.C. § 103 on the basis that the claimed subject matter would have been obvious in view of Rodriguez-Tomé.[1] The examiner characterized Rodriguez-Tomé as teaching most of the limitations of claim 58. See the Examiner's Answer, page 5. The examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905, but she concluded that the specific sequences recited in the claim represent merely nonfunctional descriptive material and therefore do not patentably distinguish the claimed method from the method of the prior art. See id., pages 6-7.

Appellants have not disputed that Rodriguez-Tomé teaches a method comprising comparing a target nucleotide sequence to a database comprising at least 100

[1] Rodriguez-Tomé et al., "The European Bioinformatics Institute (EBI) databases," Nucleic Acids Research, Vol. 24, pp. 6-12 (1996).

nucleotide sequences and identifying the target sequence as being present in the database. These limitations reasonably appear to be met by Rodriguez-Tomé. See, e.g., page 6, the paragraph bridging the columns (EMBL nucleotide sequence database, release 44, contained 506,192 entries) and page 10, section headed "Sequence search facilities" ("The EBI provides a number of services that allow users to compare their own sequences against the most currently available data in the EMBL nucleotide sequence database.").

Appellants argue, however, that the sequences recited in the claims are functional: "The sequences stored on computer readable medium are utilized in the act of comparing and thus greatly facilitate the identification, detection or ranking of nucleotide sequences within the sequences stored on computer readable medium. As such, they cannot be ignored as non-functional, descriptive material in the obviousness determination." Reply Brief, pages 3-4. "The claimed methods would not achieve their purposes (identification, detection or ranking) without the sequences recorded on a computer readable medium. . . . As such, the sequences are functionally related to the computer readable medium and therefore must be considered in the obviousness determination." Id., page 4. Appellants conclude that, since the reference does not teach the recited sequences, it does not teach or suggest all of the elements of the claimed method and therefore does not support a prima facie case of obviousness. See, e.g., the Appeal Brief, pages 21-22.

Thus, the only issue in dispute seems to be whether the specific sequences recited in claim 58 distinguish the claimed method from known methods that used other sequences. The examiner argues that the sequences are nonfunctional descriptive

material and therefore entitled to no patentable weight; Appellants argue that the sequences are functional and therefore distinguish the claimed method from the prior art.

The distinction between functional and nonfunctional descriptive material arises out of cases dealing with printed matter limitations. For example, in In re Gulack, 703 F.2d 1381, 217 USPQ 401 (Fed. Cir. 1983), printed matter that was functionally related to its substrate was held to distinguish the claimed product from the prior art. In Gulack, the claims "recite[d] three key elements: (1) a band . . .; (2) a plurality of individual digits imprinted on the band or ring at regularly spaced intervals; and (3) an algorithm by which the appropriate digits are developed." Id. at 1382, 217 USPQ at 402. With the digits generated by the algorithm printed on it, the band could be used "to perform magic tricks or to display various aspects of number theory." Id. at 1383, 217 USPQ at 402. The claims had been rejected as obvious, based on prior art that differed only in what was printed on the band. Id. at 1384, 217 USPQ at 403.

The court stated that, although limitations reciting printed matter cannot be ignored, "[w]here the printed matter is not functionally related to the substrate, the printed matter will not distinguish the invention from the prior art in terms of patentability. Although the printed matter must be considered, in that situation it may not be entitled to patentable weight." Id. at 1385, 217 USPQ at 404 (footnote omitted). The court stated that "the critical question is whether there exists any new and unobvious functional relationship between the printed matter and the substrate." Id. at 1387, 217 USPQ at 404. The Gulack court held that such a relationship had been shown; i.e., the looped structure of the substrate and the particular digits printed on it interrelated to give the

claimed product a property it would not have had if either the structure or the digits were changed. Therefore, the content of the printed matter was held to produce a nonobvious difference between the claimed product and the prior art.

By contrast, in In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004), a printed matter limitation was held to be nonfunctional and therefore inadequate to distinguish the claimed product from the prior art. Ngai claimed a kit that contained at least one of several reagents (e.g., buffer) and instructions that described a process of using the reagents to amplify RNA. Id. at 1337, 70 USPQ2d at 1863. The claim had been rejected based on prior art that disclosed a kit containing buffer and instructions, albeit instructions that described a different process. Id. at 1337, 70 USPQ2d at 1863.

The Ngai court held that the printed instructions were not related to the claimed kit in the way that Gulack's numbers were related to his band. See id. at 1339, 70 USPQ2d at 1864: "In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter. All that the printed matter does is teach a new use for an existing product." The rejection was affirmed.

A similar distinction has been recognized in the context of computer-related inventions. Compare, for example, In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994), with In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754 (Fed. Cir. 1994).[2]

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[2] We recognize that the Lowry court stated that "[t]he printed matter cases have no factual relevance where 'the invention as defined by the claims requires that the information be processed not by the mind but by a machine, the computer.'" 32 F.3d at 1584, 32 USPQ2d at 1034. This statement, however, must be regarded as dictum, because the court went on to conclude that the data structures at issue in Lowry were not analogous to printed matter. See id. Thus, the court's statement regarding the relevance of the

Both cases involved so-called "data structures". The court in Lowry concluded that the data structures were "physical entities that provide increased efficiency in computer operation" and were not analogous to printed matter. 32 F.3d at 1584, 32 USPQ2d at 1035. The Warmerdam court, however, concluded that the "data structure" claimed therein was not a physical arrangement of hardware but instead was "nothing more than another way of describing the manipulation of ideas contained in" other claims and therefore not statutory subject matter eligible for patenting. 33 F.3d at 1362, 31 USPQ2d at 1760.

Here, the descriptive material (SEQ ID NOs) recited in claim 58 is not functional material like the data structures in Lowry. Those data structures, "while including data resident in a database, depend only functionally on information content. While the information content affects the exact sequence of bits stored in accordance with Lowry's data structures, the claims require specific electronic structural elements which impart a physical organization on the information stored in memory." 32 F.3d at 1583, 32 USPQ2d at 1034. As a result, Lowry's data structures "provide increased efficiency in computer operation. They are not analogous to printed matter." Id. at 1584, 32 USPQ2d at 1035.

In this case, by contrast, there is no evidence that SEQ ID NOs 16207 to 27905 functionally affect the process of comparing a target sequence to a database. There is no evidence, for example, that these SEQ ID NOs interact with other computer hardware or software to affect the efficiency or accuracy or any other characteristic of

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printed matter cases to inventions involving computer-readable information was not essential to the holding. The Lowry court did not consider whether, and under what circumstances, computer-readable information that is analogous to printed matter can distinguish a claimed invention from the prior art.

the comparison. Rather, the SEQ ID NOs appear to be used merely as inputs for a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database. In other words, the specific SEQ ID NOs recited in the claims do not affect how the method of the prior art is performed – the method reasonably appears to be carried out the same way regardless of which specific sequences are included in the database.[3]

Thus, the descriptive material in this case is properly considered to be nonfunctional. The SEQ ID NOs recited in claim 58 are analogous to the instructions in In re Ngai. The Ngai court held that, in contrast to Gulack, the printed instructions were not functionally related to the claimed kit. See id. at 1339, 70 USPQ2d at 1864: "In Gulack, the printed matter would not achieve its educational purposes without the band, and the band without the printed matter would similarly be unable to produce the desired result. Here, the printed matter in no way depends on the kit, and the kit does not depend on the printed matter." The same is true here: the recited sequences are not functionally related to the computer system carrying out the comparison because the computer compares a target sequence to a database the same way regardless of whether the database includes any of SEQ ID NOs 16207 to 27905: the SEQ ID NOs and the computer do not depend on each other for their function.

The Ngai court also stated that "[i]f we were to adopt Ngai's position, anyone could continue patenting a product indefinitely provided that they add a new instruction

[3] Of course, the results of comparing a target sequence to a database may change depending on which sequences are included in the database. That possibility does not mean that the database sequences are functional: MP3 files encoding "America the Beautiful" and "Yankee Doodle Dandy," respectively, will cause a computer's speaker to output different songs, yet music is a paradigmatic nonfunctional

sheet to the product. . . . Ngai is entitled to patent his invention of a new RNA extraction method, and the claims covering that invention were properly allowed. He is not, however, entitled to patent a known product by simply attaching a set of instructions to that product." Id. at 1339, 70 USPQ2d at 1864.

Similarly here, if we were to adopt Appellants' position, anyone could continue patenting methods of analyzing genetic sequence data – or any other data, for that matter – provided that they included at least one new DNA sequence or other datum in a known database. Appellants have discovered what are apparently several thousand new DNA sequences from E. nidulans. They are entitled to patent the DNAs having those sequences (assuming the DNAs meet all of the statutory requirements) but they are not entitled to patent a known method of sequence comparison by merely including at least one novel DNA sequence in a database.

Our conclusion is consistent with the USPTO's recently announced examination guidelines relating to subject matter eligible for patenting. See Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility, 1300 Off. Gaz. Pat. Office 142 (November 22, 2005), especially pages 151-152. (The Manual of Patent Examining Procedure includes substantively the same guidance. See MPEP, 8th edition (revised Aug. 2005), § 2106(IV)(B)(1).)

The Patent Subject Matter Eligibility Interim Guidelines state that "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component. . . . 'Nonfunctional descriptive

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descriptive material. Thus, descriptive material is not functional merely because it results in different outputs when acted on by a computer program.

material' includes but is not limited to music, literary works and a compilation or mere arrangement of data." Page 151. When claims comprise nonfunctional descriptive material recorded on computer-readable media, the guidelines direct the examiner to

> determine whether the claimed nonfunctional descriptive material be given patentable weight. The USPTO must consider all claim limitations when determining patentability of an invention over the prior art. In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403-04 (Fed. Cir. 1983). The USPTO may not disregard claim limitations comprised of printed matter. See Gulack, 703 F.2d at 1384, 217 USPQ at 403; see also Diehr, 450 U.S. at 191, 209 USPQ at 10. However, the examiner need not give patentable weight to printed matter absent a new and unobvious functional relationship between the printed matter and the substrate. See In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994); In re Ngai, 367 F.3d 1336, 70 USPQ2d 1862 (Fed. Cir. 2004).

Pages 151-152.

Consistent with the Guidelines, the examiner in this case considered all of the limitations of the claims but declined to give patentable weight to those limitations reciting nonfunctional descriptive material; specifically, SEQ ID NOs 16207 to 27905.

Finally, a couple of points in the dissent require a response. Our dissenting colleague argues that the claimed method is analogous to a hybridization assay using nucleic acids having the sequences shown in SEQ ID NOs 16207 through 27905. He reasons that if Appellants were claiming such an assay, using actual nucleic acid molecules, the novelty of the nucleic acids would have to be considered in determining the obviousness of the method.

The short answer to that hypothetical is that Appellants are not claiming a hybridization assay, they are claiming a computer-implemented method of comparing two sets of data. The comparison seems to call for a more detailed rebuttal, though. It may seem implausible to compare a computer-based calculation and a hybridization

assay, but both approaches are ways of determining the degree of similarity between nucleic acids. Why would the structure of the nucleic acids be a factor in the obviousness analysis, when the sequences of the SEQ ID NOs is not?

The reason the dissent's hybridization method is treated differently from the claimed method comes down to the difference between chemical compounds and chemical formulas. A hybridization method combines two physical compounds and observes their interaction to determine their similarity. The claimed method reduces the nucleic acids to abstract representations of their structure (i.e., sequences of letters representing the structure of the nucleic acids) and then mathematically calculates the degree of similarity between those abstractions and another abstraction representing the structure of a target nucleic acid.

It is the reduction of the physical nucleic acids to an abstract representation of their structure that distinguishes the claimed method from the dissent's hybridization assay. When a physical object is used in a method, the obviousness of the method depends in part on the novelty of the object used – if an object was previously unknown, it can hardly be said that using that unknown object would have been obvious, even in an otherwise old method. Cf. In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir. 1995).

However, when instead the method merely manipulates data, the obviousness or nonobviousness of the method does not depend on whether the particular set of data was novel: given a known method of comparing data representing, e.g., nucleic acid structures, it would be obvious to use that method to compare any two sets of data representing nucleic acid structures, even if a particular sequence of As, Gs, Cs, and Ts

had not previously been compared to other sequences of As, Gs, Cs, and Ts. Thus, a difference only in nonfunctional descriptive material, such as data representing nucleic acids, does not make a claimed process nonobvious over a process, known in the prior art, that is otherwise identical.

This brings us to a second point on which we disagree with the dissent's analysis. The dissent argues that the SEQ ID NOs recited in claim 58 are functional descriptive material because they might change the result obtained when a target sequence is compared to the sequences in the database.[4]

We do not agree with this reasoning. As noted above (footnote 3), when music is recorded on a computer-readable medium, the sound that is output through the computer's speakers, when the music is read by an appropriate program, will depend on the specific sequence of notes that is recorded. Music, however, is widely considered to be ineligible for patent protection.[5]

Thus, descriptive material is not functional merely because it can change the output that results when a computer program reads the material from a medium. If affecting the output made descriptive material functional, then a compact disk with a song recorded on it could be patented. See the Interim Guidelines, page 151: "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in

[4] The dissent says they "will" change the results but this is true only if the target sequence is one of SEQ ID NOs 16207 through 27905: if the target sequence matches some other sequence in the database – or none at all – the result will be the same whether or not the database includes any of SEQ ID NOs 16207 through 27905.

[5] The passage from the Interim Guidelines cited by the dissent is not to the contrary. In the cited example, the nonfunctional descriptive material (musical notes) is apparently read by the computer program as a signal to play "another defined series of notes." In the instant claims, by contrast, the data

most cases." That result is clearly contrary to the prevailing interpretation of 35 U.S.C. § 101, and supports our conclusion that data that do nothing more than change the output of a computer program that read them are nonfunctional descriptive material.

Summary

The examiner's analysis and conclusion are consistent with the USPTO's examination guidelines and with the relevant case law. We therefore affirm the examiner's rejection.

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED

Toni R. Scheiner)
Administrative Patent Judge) BOARD OF PATENT
)
) APPEALS AND
)
Eric Grimes)
Administrative Patent Judge) INTERFERENCES
)

EG/jlb

(SEQ ID NOs) are merely used as inputs for comparison to a target sequence, not as functional signals to a computer program.

ADAMS, Administrative Patent Judge, dissenting.

I disagree with the majority's characterization of the sequences recited in appellants' claimed invention as non-functional descriptive material (supra, page 8). I also disagree with the majority's assertion (supra, page 1), "the obviousness of the claimed method does not depend on which sequences are being compared." In my opinion, the claimed methods require the specifically recited sequences, which are functionally related to the remaining elements of the claimed invention. Accordingly, I respectfully dissent.

I. Appellants' claimed method:

The claims before us on appeal are method claims. The majority limited their analysis to appellants' claim 58; accordingly, I focus my attention on claim 58. In this regard, I recognize the majority's construction of claim 58. Supra, pages 2-3. According to the majority (supra, page 3), "claim 58 is directed to a method that comprises comparing a target sequence to a database of at least 100 nucleotide sequences, at least one of which is included in the group of sequences represented by SEQ ID NOs 16207 to 27905." The majority fails to recognize, however, that the method of claim 58 requires as a final step, "identifying said target sequence as being present in the computer readable medium." Accordingly, I disagree with the majority's construction of the claimed invention. As set forth in In re Gulack, 703 F.2d 1381, 1385, 217 USPQ 401, 403 (Fed. Cir. 1983), the PTO must consider all claim limitations when determining patentability of an invention over the prior art – "the claim must be read as a whole." Accord In re Ochiai, 71 F.3d 1565, 1569, 37 USPQ2d 1127, 1131 (Fed. Cir.

1995) ("The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'"). Therefore, I offer the following construction of claim 58.

Initially, I note for clarity, that claim 58 as reproduced in the appendix of the Brief, appears to contain a typographical error. Specifically, the term "sequence" as it occurs in the phrase "including sequence selected from the group consisting of...." should read "sequences." See e.g., Paper received October 23, 2001, page 3, wherein claim 58 was first introduced into the record and read "... including sequences selected from the group consisting of...." It appears that this typographical error was introduced into the record on December 29, 2003, when appellants submitted an amendment to add the final clause of the claim as it now appears before us on appeal.[6] Nevertheless, I agree with the majority's interpretation of the phrase "including sequence[s] selected from the group consisting of..." to mean "at least one" sequence must be selected from the recited group. Supra, page 3.

Therefore, as I understand it, the method of claim 58 is drawn to a method of identifying a nucleotide sequence. This method comprises comparing a target sequence to a sequence stored on a computer readable media[7], e.g., a CD-ROM disc. Therefore, implicitly, if a sequence other than that required by appellants' claimed

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[6] In the event of further prosecution, I encourage the examiner to clarify this issue.

[7] For clarity, I note that appellants define the term "computer readable medium" at page 37 of their specification as,

> any medium that can be read and accessed directly by a computer. Such media include, but are not limited to: magnetic storage media, such as floppy discs, hard disc, storage medium, and magnetic tape; optical storage media such as CD-ROM; electrical storage media such as RAM or ROM; optical scanner readable medium such as printed paper; and hybrids of these categories such as magnetic/optical storage media.

method is stored on the computer readable media, the claimed method cannot be performed. In this regard, claim 58 requires the computer readable media to have recorded thereon 100 nucleotide sequences, wherein "at least one" is selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. The last clause of the method set forth in claim 58 requires that the method identify whether the target sequence is present in the sequences recorded on the computer readable media.

Against this backdrop, I now consider the merits of appellants' claimed invention.

II. In vitro versus in silico:

To begin, it may be helpful to take a step back and consider appellants' claimed invention under a different light. Particularly, out of and away from the in silico environment of a computerized process and in terms of an in vitro, "wet chemistry", process. With this in mind, instead of having sequences recorded on a computer readable medium, we have a 100 well plate with one nucleic acid molecule present in each well, wherein at least one of the nucleic acid molecules has a sequence that is selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof. In this regard, the method would be to add a target nucleic acid molecule to each of the 100 wells on the plate[8], allow a hybridization reaction to

[8] In this regard, the nucleic acid molecules function as hybridization partners for a target nucleic acid molecule having a complimentary sequence. Accordingly, if nucleic acid molecules other than those that are specifically recited are used, the method will not produce the stated result - to identify whether the target nucleic acid is present among the sequences on the 100 well plate, which includes at least one sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof.

take place under appropriate conditions and then after appropriate washing conditions, identify if the target sequence hybridized to any of the nucleic acid sequences on the plate, thereby identifying said target sequence as being present on the plate.

In my opinion, under the foregoing scenario, the examiner and the majority would be hard pressed to give little patentable weight to the specific sequences recited in method. Likewise, if the specific nucleic acid molecules were not known in the art prior to appellants' filing date, the examiner and the majority would be hard pressed to maintain an obviousness rejection, over a prior art reference that taught the same method but used different nucleic acid molecules. In this respect, the foregoing scenario is analogous to In re Ochiai, 71 F.3d 1565, 37 USPQ2d 1127 (Fed. Cir. 1995). In Ochiai, the claims were directed to a method of making a novel and nonobvious product, from a novel and nonobvious starting material, via a standard chemical reaction. See id. at 1567, 37 USPQ2d at 1129. The examiner rejected the claimed method and the Board affirmed, on the basis that

> [t]he process steps, "introducing" A into AB or "reacting" A with B are standard processes used by practitioners in the prior art for reacting similar A moieties with the same B moiety. We are in agreement with the examiner that there is nothing unobvious in the particular process chosen and claimed by the appellants.

Id. at 1569, 37 USPQ2d at 1130 (emphasis in original).

The Federal Circuit reversed, because the PTO had impermissibly ignored limitations of the claimed method in evaluating its patentability over the prior art. "The test of obviousness vel non is statutory. It requires that one compare the claim's 'subject matter as a whole' with the prior art 'to which said subject matter pertains.'" Id.

at 1569, 37 USPQ2d at 1131. The court noted that

> [t]he process invention Ochiai recites in claim 6 specifically requires use of none other than its new, nonobvious acid as one of the starting materials. One having no knowledge of this acid could hardly find it obvious to make any cephem using this acid as an acylating agent, much less the particular cephem recited in claim 6. In other words, it would not have been obvious to those of ordinary skill in the art to choose the particular acid of claim 6 as an acylating agent for the known amine for the simple reason that the particular acid was unknown but for Ochiai's disclosure. . . . As one of our predecessor courts had occasion to observe, in a case involving a highly analogous set of facts, "one cannot choose from the unknown." Mancy, 499 F.2d [1289,] 1293, 182 USPQ [303,] 306 [(CCPA 1974)].

Id. To paraphrase the Ochiai court, it would not have been obvious to a person of ordinary skill in the art at the time the invention was made to select a nucleic acid molecule having a sequence selected from the group consisting of SEQ ID NO: 16207 through SEQ ID NO: 27905 and complements thereof, for the simple reason that these particular nucleic acids (defined by SEQ ID NO.), were unknown prior to appellants' disclosure.

On this record, the majority recognizes (supra, page 3), "[t]he examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905...." Stated differently, but for appellants' disclosure, the recited sequences were new and unobvious. In this regard, the majority concedes (supra, page 9), "[a]ppellants have discovered what are apparently several thousand new DNA sequences from E. nidulans. They are entitled to patent the DNAs having those sequences (assuming the DNAs meet all of the statutory requirements)." Nevertheless, despite the examiner and majority's recognition that the recited sequences were not known in the art, prior to appellants' filing date, an obviousness rejection is sustained

over a reference that teaches the claimed process using different nucleotide sequences. Accordingly, I am unable to ratify the majority's decision with the law as understand it.

In essence, all that appellants have done is take a method of identifying a target sequence out of and away from an in vitro environment and place it in silico. As I understand the majority's opinion, by placing the method in silico, the functional relationship between the recited nucleic acid molecules, identified by SEQ ID NOs., and the remaining elements of the claimed method is lost. In my opinion, the facts on this record do not support this conclusion.

III. Statutory subject matter:

Upon consideration of the majority's opinion, it appears that the majority has excised the recited sequences from appellants' claimed method and reconstructed appellants' method to be something that it is not. As a result, the majority enters into a discussion of the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines)[9], 1300 Off. Gaz. Pat. Office 142 (November 22, 2005), and In re Warmerdam, 33 F.3d 1354, 31 USPQ2d 1754 (Fed Cir. 1994)[10]. To be clear, however, there is no dispute on the record before us on this

[9] As set forth on page 142, column 2, second full paragraph of the Interim Guidelines, "[t]he principal objective of these guidelines is to assist examiners in determining, on a case-by-case basis, whether a claimed invention falls within a judicial exception to statutory subject matter ... or whether it is a practical application of a judicial exception to statutory subject matter."

[10] In Warmerdam, the court held that claims reciting a method for creating a data structure which controlled the motion of objects did not constitute patent eligible subject matter.

appeal as to whether appellants' claimed method is patent eligible subject matter.[11] Since the issue as to whether the claimed invention is patent eligible subject matter is not before us I will not discuss this issue, except to highlight what I consider to be the majority's incorrect interpretation of appellants' claimed invention.

According to the majority (supra, page 8), "the SEQ ID NOs appear to be used merely as inputs for a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database." Contrary, to the majority's assertion, the claimed invention is not "a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database." Instead, the claimed invention is a method of identifying a nucleotide sequence. While the claimed method comprises a comparison step, the claimed result of the method is to identify said target sequence as being present in the computer readable medium.

Further, even if the majority is correct in that the specific sequences recited in appellants' claim are simply data elements for use with a computer program that calculates the degree of similarity between a target sequence and each of the data elements, the Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines), 1300 Off. Gaz. Pat. Office 142 (November

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[11] At best, during prosecution, the examiner questioned the utility of appellants' claimed invention under 35 U.S.C. §§ 101 and 112, first paragraph, and invited appellants to "identify a specific, substantial, and credible utility for the claimed invention and establish a probative relation between any evidence of record and the originally disclosed properties of the claimed invention." Office Action, mailed October 6, 2003, page 4. In response, appellants directed the examiner attention, inter alia, to the "disclosed use of the claimed methods ... in the detection of the presence, absence or level of an organism, for example E. nidulans, in a given sample. See, e.g. page 37, lines 7 through 9 and page 30, lines 19 through 21." Response, received December 29, 2003, page 9; Accord, Brief, pages 6-9. As set forth on page of the Answer, the examiner subsequently withdrew the rejection under 35 U.S.C. §§ 101 and 112, first paragraph.

22, 2005), states (page 151, citation omitted), "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of 'data structure' is 'a physical or logical relationship among data elements, designed to support specific data manipulation functions.' ...)." Thus, it would appear, that even if the claimed database of sequences is used merely as inputs for a computer program, it would appear to fulfill the requirements of "functional descriptive material" as set forth in the Interim Guidelines.

However, faced with legal precedent and Interim Guidelines that fail to support their position, the majority introduces a music analogy to emphasize their point, and further disassociate the sequences set forth in appellants' claim from the underlying method. In this regard, the majority asserts (supra, n. 3), "MP3 files encoding 'America the Beautiful' and 'Yankee Doodle Dandy,' respectively, will cause a computer's speaker to output different songs, yet music is a paradigmatic nonfunctional descriptive material." According to the majority, their findings are consistent with the USPTO's recently announced Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility (Interim Guidelines), 1300 Off. Gaz. Pat. Office 142 (November 22, 2005), particularly, page 151, "'Nonfunctional descriptive material' includes but is not limited to music, literary works and a compilation or mere arrangement of data." In my opinion, this analysis is not consistent with the facts in this case.

For the majority's analogy to be consistent with this case appellants' claimed invention would be drawn to a compilation of sequences on a CD-Rom disc.[12] This is, however, not the invention before us on appeal. Instead, appellants' claimed method is drawn to a method wherein a computer program is used to compare a target sequence with a database of sequences to identify whether the target sequence is present in the database of sequences. To use the majority's music analogy, the Interim Guidelines, provide an example that, in my opinion, is more on point with appellants' claimed invention than the analogy provided by the majority. Specifically, the Interim Guidelines state (page 152)

> a computer that recognizes a particular grouping of musical notes read from memory and upon recognizing that particular sequence, causes another defined series of notes to be played, defines a functional interrelationship among that data and the computing processes performed when utilizing that data, and as such is statutory because it implements a statutory process.

Similarly, appellants' claimed method is drawn to a method wherein a computer program compares a target sequence to sequences recorded on a computer readable medium, and upon the conclusion of this comparison identifies whether the target sequence is present among the sequences recorded on the computer readable medium. In my opinion, this defines a functional interrelationship among the data and the computing processes performed when utilizing that data. Accordingly, contrary to

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[12] Note, for example, that this was the subject matter of now canceled claim 29, which was drawn to a "[c]omputer readable medium having recorded thereon at least 100 of the nucleotide sequences depicted in SEQ ID NO: 16207 through SEQ ID NO: 27905 or complements thereof." In the First Office Action on the Merits (mailed May 23, 2001, page 3), the examiner rejected claim 29 under 35 U.S.C. § 101, as drawn to non-statutory subject matter. In response appellants canceled the claim. Response, received October 23, 2001, page 2.

the majority's assertion, it is my opinion that the Interim Guidelines do not support their position.

IV. Functional versus non-functional descriptive material:

According to claim 58, if a target sequence has a sequence defined by one of appellants' recited sequences (e.g., SEQ ID NO: 16207), the claimed method will identify the target sequence as being present in the computer readable medium only if appellants' specifically recited sequence (e.g., SEQ ID NO: 16207), is present among the sequences recorded on the computer readable media. In this regard, I note, there is no evidence on this record that the claimed method can be practiced without the use of the sequences required by appellants' claimed method. Thus, it would appear that the sequences recited in appellants' claimed invention are functionally related to the method, without which the method will not function as claimed.

There is no evidence on this record that any of the sequences identified as SEQ ID NO: 16207 through SEQ ID NO: 27905, were known in the art prior to appellants' filing date.[13] According to appellants' specification (page 4), the sequences set forth in SEQ ID NO: 16207 through SEQ ID NO: 27905 are "genes or partial genes of the E. nidulans genome." In this regard, I note that appellants' specification discloses (page 30), "one or more of the agents of the present invention may be used to detect[ ] the presence, absence or level of ... E. nidulans in a sample." Therefore, as I understand it, the method of claim 58 can be used to detect the presence, absence or level of E.

[13] As the majority points out (supra, page 3), "The examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905...."

nidulans in a sample, by identifying whether a target sequence obtained from a sample is present in the sequences recorded on the computer readable medium. There is no evidence on this record that the claimed method would be able to detect E. nidulans in a sample without appellants' recited sequences.

Nevertheless, in contrast to the foregoing discussion, the majority finds (supra, page 1), "the obviousness of the claimed method does not depend on which sequences are being compared." According to the majority (supra, page 8), "the recited sequences are not related to the computer system carrying out the comparison because the computer compares a target sequence to a database the same way regardless of whether the database includes any of SEQ ID NOs 16207 to 27905: the SEQ ID NOs and the computer do not depend on each other for their function." I agree with the majority, that a particular computer program[14] that is used to compare sequences (e.g., BLASTIN), will compare a target sequence to a database the same way regardless of whether the database includes the sequences required by appellants' claimed method. There is, however, no evidence on this record to suggest that one practicing the method

[14] According to appellants' specification (page 38, lines 13-15), "[c]omputer software is publicly available which allows a skilled artisan to access sequence information provided in a computer readable medium." In addition, Rodriguez-Tomé teach (page 7, column 1, lines 38-41), "the EBI [(European Bioinformatics Institute)] maintains a repository of biology related software on its network servers. This software is also distributed once a year on CD-ROM." Further, I note that claim 58 does not require the use of any particular means for performing the comparison. Therefore, as disclosed in appellants' specification, and taught by Rodriguez-Tomé, methods of identifying a nucleotide sequence by comparing a target sequence to a sequence stored in computer readable medium was known in the art prior to the date of appellants' claimed invention. As the majority points out (supra, bridging paragraph, pages 3-4), there is no dispute on this record that computer programs for comparing sequences were known in the art prior to appellants' filing date.

of claim 58 could obtain the same result[15] required by the method, without using the new and unobvious sequences required by the claim. Therefore, I disagree with the majority's assertion (supra, page 1), "the obviousness of the method does not depend on which sequences are being compared."[16]

I disagree with the majority's characterization of the claimed sequences as non-functional descriptive material. Supra, page 8. As appellants point out (Reply Brief, page 4), "[t]he claimed methods would not achieve their purposes (identification, detection or ranking) without the sequences recorded on a computer readable medium. ... As such, the sequences are functionally related to the computer readable medium and therefore must be considered in the obviousness determination." I agree.

Nevertheless, the majority relies on Ngai, to support their position that the sequences set forth in appellants' claimed method are non-functional descriptive material. Supra, pages 8-9. In my opinion, Ngai does not support the majority's conclusion on the facts of this record. In Ngai, the claim[17] at issue was drawn to a kit for normalizing and amplifying an RNA population. Ngai's kit comprised two components:

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[15] Identifying whether the target sequence is present among the sequences specifically recited in appellants' claimed invention. Thus, contrary to the majority's assertion the SEQ ID NOs and the computer [program] do depend on each other for their function. The computer program would not be able to identify whether a target sequence is among the new and unobvious sequences set forth in appellants' claimed invention if those sequences are not present in the "database".

[16] See, In re Spormann, 363 F.2d 444, 448, 150 USPQ 449, 452 (CCPA 1966), "[o]bviousness cannot be predicated on what is unknown." Cf. In re Lowry, 32 F.3d 1579, 1583, 32 USPQ2d 1031, 1034-35 (Fed. Cir. 1994), quoting In re Bernhart, 417 F.2d 1395, 1400, 163 USPQ 611, 616 (CCPA 1969) ("if a machine is programmed in a certain new and unobvious way, it is physically different from the machine without that program; its memory elements are differently arranged. The fact that these physical changes are invisible to the eye should not tempt us to conclude that the machine has not been changed.").

[17] Claim 19 was the only claim on appeal in Ngai. During prosecution, the examiner indicated that Ngai's method claims, claims 1-18, were allowable. In addition, the Board reversed the examiner's obviousness rejection of Ngai's only remaining claim, claim 20, which was drawn to a kit. Accordingly, claim 20 was not at issue on appeal.

(1) a product (e.g., a buffer), and (2) instructions for the use of the product. In Ngai, the prior art relied upon in the anticipation rejection taught a kit comprising a buffer and instructions[18]. Ngai, at 1337, 70 USPQ2d at 1863. Accordingly, in Ngai, "the only difference between the prior art and [Ngai's] claim 19 is the content of the instructions." Id. On the facts in Ngai, the court found, "[a]ll that the printed matter does is teach a new use for an existing product." Ngai, at 1339, 70 USPQ2d at 1864. In this regard, it has long be held that a claim to an otherwise old composition cannot be distinguished from the prior art simply by asserting a new use for the composition. See e.g., In re Pearson, 494 F.2d 1399, 1403, 181 USPQ 641, 644 (CCPA 1974) ("terms [that] merely set forth the intended use for ... an otherwise old composition ... do not differentiate the claimed composition from those known in the prior art.").

In contrast to Ngai, on this record, the majority admits (supra, n. 3), "the results of comparing a target sequence to a database may[19] change depending on which sequences are included in the database." Stated differently, in the method before us on this record, the claimed method will provide a different result if the sequences set forth in appellants' claims are not used. Accordingly, I disagree with the majority's conclusion (supra, page 8), "[t]he SEQ ID NOs recited in claim 58 are analogous to the instructions in In re Ngai." Where in Ngai, the instructions did not affect the product, here appellants' recited sequences, play a critical role in the claimed method, and will directly affect the result of the claimed method.

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[18] As the majority points out (supra, page 6), the instructions in the prior art differed from Ngai's instructions.

[19] While the majority uses the term "may", there is no evidence on this record that the same result would be obtained using sequences other than those required by appellants' claimed invention.

Further, while the majority agrees that appellants' claimed method will lead to a different result if the claimed sequence is not used, the majority dismisses this seemingly critical fact by "classifying" the sequences recited in claim 58 as non-functional descriptive material. Supra, page 8. To emphasize this point the majority attempts to distinguish the sequences recorded on a computer readable medium from the "data structures" in In re Lowry, 32 F.3d 1579, 32 USPQ2d 1031 (Fed. Cir. 1994). In this regard, the majority finds (supra, pages 7-8), in contrast to Lowry,

> there is no evidence that SEQ ID NOs 16207 to 27905 functionally affect the process of comparing a target sequence to a database. There is no evidence, for example, that these SEQ ID NOs interact with other computer hardware or software to affect the efficiency or accuracy or any other characteristic of the comparison. ... [T]he SEQ ID NOs appear to be used merely as inputs for a computer program that calculates the degree of similarity between a target sequence and each of the sequences in a database. ... [T]he specific SEQ ID NOs recited in the claims do not affect how the method of the prior art is performed....

The majority's argument, however, appears to be somewhat inconsistent with their other findings. On one hand the majority finds (supra, n. 3), "[o]f course, the results of comparing a target sequence to a database may change depending on which sequences are included in the database." On the other hand, the majority finds (supra, pages 7-8, footnote omitted), "[t]here is no evidence that SEQ ID NOs 16207 to 27905 functionally affect the process of comparing a target sequence to a database ... the specific SEQ ID NOs recited in the claims do not affect how the method of the prior art is performed – the method reasonable appears to be carried out the same way regardless of which specific sequences are included in the database." It's hard to imagine how the results obtained from the claimed method could change depending on which sequences are included in the database, in the absence of a functional

relationship between the recited sequences and the other elements of the claimed method.

Further, as discussed above, even if the majority is correct in that the specific sequences recited in appellants' claim are simply data elements for use with a computer program that calculates the degree of similarity between a target sequence and each of the data elements, the Interim Guidelines states (page 151, citation omitted), "'functional descriptive material' consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of 'data structure' is 'a physical or logical relationship among data elements, designed to support specific data manipulation functions.' ...)." In the context of appellants' claimed invention, the sequences recorded on the computer readable medium are essentially the electronic equivalent to a "hybridization partner" for the "target sequence." Thus, it would appear, that even if the claimed database of sequences is used merely as inputs for a computer program, it would appear to fulfill the requirements of "functional descriptive material" as set forth in the Interim Guidelines.

Accordingly, it is my opinion that the precedent relied upon by the majority fails to support their finding that the sequences as recited in appellants' claimed invention should be classified as "non-functional descriptive material," and therefore given no patentable weight in the context of appellants' claimed invention.

V. Public policy considerations:

I recognize the majority's concern (supra, page 9), "if we were to adopt Appellants' position, anyone could continue patenting methods of analyzing genetic

sequence data – or any other data, for that matter – provided that they included at least one new DNA sequence or other datum in a known database." I find the majority's concern troubling for two reasons. First, as our appellate reviewing court explained in In re Fisher, 421 F.3d 1365, 1378, 76 USPQ2D 1225, 1235 (Fed. Cir. 2005), such public policy considerations are not to "affect the determination of whether an invention satisfies the requirements set forth in 35 U.S.C. §§ 101, 102, 103, and 112. Second, as I understand the majority's concern, anyone could continue to advance the useful arts by seeking patent protection on methods of analyzing genetic sequence data using previously unknown DNA sequences[20]. While the majority's argument is based on a similar statement in Ngai, it must be emphasized that the court's statement in Ngai was directed at the continued patenting of a known product, simply by adding a new instruction sheet to the product. This is not same as the method before us on this record. There is no evidence on this record that claimed method will produce the same result if sequences other than those recited in appellants' claim are used. To the contrary, the majority recognizes that a different result will be obtained if appellants' sequences are not used. Supra, n. 3. Accordingly, it is unclear how the majority can conclude that the sequences are not functionally related to the remaining elements of the method. Cf. Gulack and Ngai. It is also unclear how the majority can find the claimed method to be obvious when the sequences recited in appellants claim are new and non-obvious. Cf. Ochiai.

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[20] According to the majority (supra, page 9), appellants are entitled to patent the new DNA sequences from E. nidulans that they have discovered "but they are not entitled to patent a known method of sequence comparison by merely including at least one novel DNA sequence in a database." In this regard, the majority notes (supra, page 3), "[t]he examiner acknowledged that Rodriguez-Tomé does not teach any of the sequences of SEQ ID NOs 16207 to 27905...."

VI. Conclusion:

In my opinion, the sequences recited in appellants' claim are functionally related to the remaining elements of the method. There is no evidence on this record that the sequences recited in appellants' claim where known or obvious to one of ordinary skill in the art at the time of appellants' invention. Therefore, giving weight to the sequences as recited in appellants' method, the claimed method is not taught or suggested by Rodriguez-Tomé, the only reference relied upon in the rejection of record.

Accordingly, I would reverse the rejection of claims 58-72 under 35 U.S.C. § 103 as being unpatentable over Rodriguez-Tomé.

Donald E. Adams
Administrative Patent Judge

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